

Patricia Zettler

Direct Purchaser Plaintiffs' expert Patricia Zettler is a law professor at The Ohio State University and a former associate chief counsel in FDA's Office of Chief Counsel. She is an expert in FDA's Risk Evaluation and Mitigation Strategies (REMS) and FDA's regulation of prescription drug promotion. Ms. Zettler opines that Reckitt's conduct during the development of a shared REMS ("SSRS") for Suboxone and its generics delayed approval of the SSRS until February 2013. She also opines that, had Reckitt told FDA and the generic manufacturers from the outset that it would not cooperate in the SSRS negotiations, the generics would have obtained approval of the SSRS earlier (between August 22, 2012 and September 1, 2012). Ms. Zettler also explains the relevant history and purpose of FDA's REMS regulations and the FDA's regulations governing promotion of drug products. Additionally, Ms. Zettler issues two opinions with respect to the comparative promotion of Suboxone film to Suboxone tablets:

- 1) Reckitt's claims that Suboxone film was superior to Suboxone tablets because it was (a) less prone to misuse, abuse, and diversion, and (b) able to reduce pediatric exposures, were false or misleading and in violation of relevant laws, regulations, and FDA policies, because Reckitt lacked the type of data required by the FDA to support the comparative claims at the time they were made.
- 2) If Ms. Zettler were an attorney counseling a company such as Reckitt, she would have advised it not to make the false or misleading statements.

In rebuttal, Ms. Zettler responds to criticism by Reckitt's experts Mr. Bradshaw and Dr.

Fleischer. Regarding REMS, Ms. Zettler rebuts their assertions concerning FDA's oversight and authority and her opinions regarding the SSRS negotiations (including the timeline of events absent Reckitt's involvement). Regarding promotion, Ms. Zettler responds to criticism related to FDA standards governing promotional activities and Reckitt's comparative superiority claims.

Ms. Zettler's opening report was 64 pages, her rebuttal was 33 pages, and her supplemental rebuttal concerning the Kinard deposition (filed pursuant to the Court's Order, and incorporating the late discovery allowed by the Court) was 3 pages.